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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 1998N-0583 -- Exports; Notification and Recordkeeping Requirements, Advance notice of proposed rulemaking

Dear Madam or Sir:

Eli Lilly and Company ("Lilly") submits this comment to the advanced notice of proposed rulemaking that the Food and Drug Administration (FDA or Agency) published on June 1, 2004, announcing that the Agency is "considering whether to revise its regulations pertaining to export notification and recordkeeping." 69 Fed. Reg. 30842 (June 1, 2004). This advanced notice of proposed rulemaking was in response to a petition filed on behalf of food and cosmetic industry concerns. Lilly requests the following clarification/confirmation to ensure that any revisions will not result in an unintended burden on the pharmaceutical sector. Lilly is a leading, innovation-driven corporation committed to developing pharmaceutical products that help people live longer, healthier, and more active lives.

In its advanced notice of proposed rulemaking, FDA invited comments on "[w]hat records should an exporter have to show that the export does not conflict with the foreign country's laws?" *Id.* at 30842. Lilly requests that the Agency confirm that proof of foreign marketing authorization is sufficient to meet this requirement.

Under FDA's current rule, appropriate documentation "may" consist of either a letter from an appropriate foreign government agency "stating that the product has marketing approval from the foreign government or does not conflict with that country's laws" or a "certification by a responsible company official" in the United States. 21 C.F.R. § 1.101(b)(2). The preamble to this final rule explains that "approval letters or other government-issued documents indicating government approval are acceptable to show that the product is not in conflict with" the country of import's laws. 66 Fed. Reg. 65249, 65436 (Dec. 19, 2001). Lilly requests FDA clarify that no additional documentation is required.

It would be burdensome and unreasonable to expect a company to obtain a separate letter from a foreign government or require a certification when that company has obtained a marketing authorization in the importing country. Any new rulemaking should therefore clarify that marketing authorization in the importing country sufficiently documents that the exported drug does not conflict with the importing country's laws. Additionally, FDA should confirm that in the case of non-approved drugs, a verification that local authorization and/or regulatory approvals has been attained is adequate. For example, in the case of clinical trials this may include documentation of IRB/IEC approval or local health authority authorization. A separate letter or company certification would be an unnecessary burden when a company has secured local approval of the clinical trial application or protocol.

However, to avoid any uncertainty when a company elects to prepare a certification, Lilly request that FDA clarify who may prepare the document. As noted above, under FDA's current regulations, one means to comply with the export records requirement is "a notarized certification by a responsible company official in the United States that the product does not conflict with the laws of the importing country." 21 C.F.R. § 1.101(b)(2). The petition precipitating the advanced notice of proposed rulemaking equates a "responsible company official" with a "high-ranking company official." *See* 69 Fed. Reg. at 30844. The Agency, however, notes that it does "not necessarily equate 'responsible' with 'high-ranking.'" *Id.* Lilly requests that FDA explicitly confirm that the two terms are not synonymous and clarify what level of responsibility will suffice. Lilly further seeks confirmation that the responsible official need not be an attorney.

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Lilly appreciates this opportunity to comment on this advanced notice of proposed rulemaking.

Sincerely,

Monique Hunt McWilliams
Counsel
Eli Lilly and Company